Supplier performance and reliability as good as it should be?

### Film Forming and Coating Polymers
- Modified starch-based polymers - LYCOAT®
- Tablet coating - LYCOAT® RS
- Ready to use system – ReadLYCOAT™
- Thin film delivery systems – LYCOAT® NG

### Fast Dissolve and Chewable Tablets (ODT)
- Mannitol powders - PEARLITOL® C
- Mannitol compound - PEARLITOL® Flash
- Sorbitol powders - NEOSORB® P
- Xylitol powders - XYLISORB®

### Diluents and Fillers for Tablets/capsules
- Mannitol powders - PEARLITOL® C
- Starches (native, modified and pregelatinized)
- Maltodextrin - GLUCIDEX®
- Maltitol powders - SweetPearl™
- Partially pregelatinized starch – LYCATAB® C
- Dextrose

### Direct Compression
- Mannitol powders - PEARLITOL® DC and SD
- Sorbitol powders - NEOSORB® P and NEOSORB® P DC
- Xylitol powders - XYLISORB® DC
- Partially pregelatinized starch – LYCATAB® C
- Mannitol compound – PEARLITOL® Flash
- Maltitol powders – SweetPearl™ DC
- Co-processed starch and lactose – STARLAC®
- Betacyclodextrin for direct compression – KLEPTOSE® DC

### Binders for wet granulation
- Pregelatinized starch – LYCATAB® PGS
- Maltodextrin – LYCATAB® DSH

### Molecular encapsulation, Taste-Masking and Dissolution Enhancer
- Betacyclodextrin – KLEPTOSE®
- Methyl Cycloextrin – CRYSMEB
- Hydroxy-Propyl Betacyclodextrin – KLEPTOSE® HP and HPB

### Syrups, Semi-Solids and Softgels
- Liquid Sorbitol - NEOSORB® 70%
- D-Sorbitol and sorbitan solution – POLYSORB® 85/70/00 as plasticizer
- Maltitol syrup – LYCASIN®

### Pyrogen-Free Carbohydrates for Injectable and Dialysis Solutions
- Dextrose – LYCADEX® PF
- Sorbitol – NEOSORB® PF
- Mannitol – PEARLITOL® PF
- Sodium Gluconate Pharma
- Hydroxy-Propyl betacyclodextrin – KLEPTOSE® HP and HPB Parenteral grades

### Disintegrants and Superdisintegrants
- Wheat starch, corn starch, potato starch
- Sodium starch glycolate – GLYCOLYS®
- Co-processed starch and CaCO3 – LYCATAB® Mineral
- Chlorella microalgae – ALGOMED®

### Dietary Fiber, Proteins and Mineral Supplements
- Soluble dextrin - NUTRIOSE® FB and NUTRIOSE® FM
- Non-GMO pea protein – NUTRALYS®
- Co-processed starch and CaCO3 – LYCATAB® Mineral
- Chlorella microalgae – ALGOMED®

**ROQUETTE**, through its production units (in Europe, in Asia and in the United States) and its international distribution network, will assure a constant quality of products and services throughout the whole world.

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[www.roquettepharma.com](http://www.roquettepharma.com)
New taste masking Solutions

Enhanced solubility of API

<table>
<thead>
<tr>
<th></th>
<th>Pure Water</th>
<th>KLEPTOSE® Linecaps 17 (100 mg/ml)</th>
</tr>
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<tbody>
<tr>
<td>Hydrocortisone</td>
<td>0.32 ± 0.05</td>
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<td>Ketoprofen</td>
<td>0.22 ± 0.04</td>
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Good complexation

<table>
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<tr>
<th>Carrier</th>
<th>Ligand</th>
<th>Complex level</th>
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<tr>
<td>Menthol</td>
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<td></td>
</tr>
<tr>
<td>Methyl paraben</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Propyl paraben</td>
<td>100%</td>
<td></td>
</tr>
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</table>

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**KLEPTOSE**® Linecaps

is a good taste masking technology applicable for:

- A wide range of dosage forms: liquids, chewable tablets, ODT, suspensions...

- Cost effective solution for OTC and nutraceutical products (ex: herbal products)

**KLEPTOSE**® Linecaps

is a pea maltodextrin which forms a flexible adaptable amylose helix freely soluble in water

Amylose derived from pea starch is organized in helices with a hydrophilic external surface due to the presence of hydroxyl groups and with a hydrophobic internal surface due to the presence of hydrogen atoms. This helical structure confers the amylose the necessary characteristics for the encapsulation of active principles or flavourings. Amylose is capable of masking bitter taste of drugs by decreasing the overall amount of drug particles exposed to taste buds.

<table>
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<tr>
<th>Mw</th>
<th>Solubility in water</th>
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<tr>
<td>12000</td>
<td>Very soluble</td>
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</table>

**Masking bitter taste of paracetamol**

The taste profile of Paracetamol solutions has been determined in presence of **KLEPTOSE**® Linecaps 17 using a taste sensing system SA 402B, Insent Inc., Japan, equipped with 7 lipid membrane sensors. The use of **KLEPTOSE**® Linecaps 17 reduces the bitterness of paracetamol.

**Encapsulating agent in 1:1 and 2:1 molar ratio**

<table>
<thead>
<tr>
<th>Paracetamol</th>
<th>KLEPTOSE® Linecaps 17</th>
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<tbody>
<tr>
<td>150 mg</td>
<td>2 mg/ml</td>
</tr>
<tr>
<td>75 mg</td>
<td>2 mg/ml</td>
</tr>
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Key Technical benefits – Tested and Approved based on data available

- **New taste masking Solutions**
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PEARLITOL® Flash
MELT-IN-THE-MOUTH MAGIC WITH MANNITOL?
• A uniquely pleasing taste experience ........................................................ page 3
  • An intrinsic composition ................................................................. page 4
  • No superdisintegrant required ......................................................... page 4
  • A low lubricant level required ........................................................ page 5

• Robust tablets ..................................................................................... page 7
  • Excellent compactibility ................................................................. page 8
  • Good dilution potential ................................................................. page 9
  • Impact of tableting speed ............................................................. page 10

• Quick disintegration ........................................................................ page 11
  • In vivo disintegration test ............................................................... page 12
  • Pharmacopoeial testing ............................................................... page 13
  • In vitro test correlated with in vivo test ....................................... page 14

• Easy formulation ............................................................................... page 15

• PEARLITOL® Flash ........................................................................ page 17
  • Definition and regulation ................................................................. page 18
  • Powder characteristics ................................................................. page 18
  • Particle size ................................................................................... page 19
  • Low hygroscopicity ....................................................................... page 19
A uniquely pleasing taste experience
A uniquely pleasing taste experience

PEARLITOL® Flash gives orodispersible tablets (ODT) of exceptional taste thanks to its:

- intrinsic composition
- self-disintegrating properties
- low level of lubricant required

An intrinsic composition

PEARLITOL® mannitol is already well-known for its pleasant and mild sweet taste.

With PEARLITOL® Flash, a mannitol starch compound, orodispersible tablets melt in the mouth with a very creamy, smooth texture and a uniquely pleasing taste experience.

No superdisintegrant required

To achieve rapid disintegration of orodispersible tablets, superdisintegrants are usually added in large quantity and can impair the mouthfeel.

PEARLITOL® Flash is a self-disintegrating mannitol compound so no superdisintegrant is required in the formulation of orodispersible tablets.
A uniquely pleasing taste experience

A low lubricant level required

Using PEARLITOL® Flash, 0.4% lubricant is sufficient to ensure a direct compression process. This also contributes to a better taste of the tablet, as high levels of lubricant produce a taste that many consumers find objectionable. At 0.3% ejection force drastically increased. Above 0.4% no significant differences were observed in the compression process and in tablet characteristics. Hence the optimum lubricant level in the tested conditions is 0.4%.

Ejection force as a function of lubricant ratio

Trials were carried out on a single-punch press Korsch XP1 fitted with 13mm diameter flat punches with bevelled edges. Magnesium stearate (Barlöcher vegetal) was used as lubricant at levels varying from 0.3% to 1.2%.

Better compliance thanks to a uniquely pleasing taste experience, largely appreciated from paediatrics to geriatrics.

Clean labelling with two long-established ingredients of natural origin that opens up opportunities in nutraceutical formulations.
Robust tablets

Roquette PEARLITOL® Flash: Melt-in-the-mouth magic with mannitol
**Robust tablets**

**PEARLITOL® Flash has been specifically designed for orodispersible tablets using a Direct Compression process.**

PEARLITOL® Flash enables the production of high quality orodispersible tablets, with classical Direct Compression.

A 15 kN compression force is sufficient to obtain tablets with suitable hardness, friability and disintegration time characteristics as illustrated below.

<table>
<thead>
<tr>
<th>Compression force (kN)</th>
<th>Disintegration time (s)</th>
<th>Hardness (N)</th>
<th>Friability (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>120</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>15</td>
<td>100</td>
<td>80</td>
<td>1</td>
</tr>
<tr>
<td>20</td>
<td>80</td>
<td>60</td>
<td>1.5</td>
</tr>
<tr>
<td>25</td>
<td>60</td>
<td>40</td>
<td>2</td>
</tr>
</tbody>
</table>

Trials carried out on a Korsch XP1 press fitted with 13mm diameter flat bevelled-edge punches. 500 mg orodispersible tablets, evaluated using Pharmacopoeial Tests.
Robust tablets

Good dilution potential

PEARLITOL® Flash makes it possible to produce very robust tablets, even at high dilution. Dilution potential is illustrated with acetaminophen.

Trials carried out on a Korsch XP1 press fitted with 13mm diameter flat bevelled-edge punches. 500 mg orodispersible tablets, evaluated using Pharmacopoeial Tests. Results shown for a 25 kN compression force.
Impact of tabletting speed

Trials were carried out on a single-punch press with a tabletting speed varying from 10 to 60 tablets / minute. Tabletting speed has limited impact on disintegration time.

Disintegration time as a function of tabletting speed

Trials carried out on a Korsch XP1 press fitted with 13mm diameter flat bevelled-edge punches, 500 mg orodispersible tablets, evaluated using Pharmacopoeial Tests. Results shown for a 15 kN compression force.

Classical Direct Compression equipment can be used, thanks to excellent compactibility.
Robustness of tablets allows traditional blister packaging to be used.
Quick disintegration
Quick disintegration is the key parameter for orodispersible tablets. Consumers expect a complete disintegration in about 30-40s. In vivo and in vitro tests have been developed to measure this time on tablets.

Quick disintegration

In vivo disintegration test

Tests have been carried out on tablets containing different actives to evaluate the in vivo disintegration time. Tablets formulas and characteristics are given in the table below.

<table>
<thead>
<tr>
<th></th>
<th>Hydrochlorothiazide tablets</th>
<th>Sodium fluoride tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEARLITOL® Flash</td>
<td>94.6%</td>
<td>97.4%</td>
</tr>
<tr>
<td>Active</td>
<td>5.0%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>0.4%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Weight (mg)</td>
<td>505.4 ± 0.7</td>
<td>104.4 ± 0.2</td>
</tr>
<tr>
<td>Thickness (mm)</td>
<td>2.96 ± 0.01</td>
<td>1.93 ± 0.01</td>
</tr>
<tr>
<td>Hardness (N)</td>
<td>77.4 ± 1.3</td>
<td>82.8 ± 2.3</td>
</tr>
<tr>
<td>Friability (%)</td>
<td>0.26</td>
<td>0.16</td>
</tr>
</tbody>
</table>

Trials were carried out on a Korsch XP1 press, fitted with 13mm diameter flat bevelled-edge punches for hydrochlorothiazide tablets and fitted with 7mm diameter flat bevelled-edge punches for sodium fluoride tablets.
Quick disintegration

In *vivo* disintegration time was measured by a panel of 8 people. Results are given below.

<table>
<thead>
<tr>
<th></th>
<th>Hydrochlorothiazide tablets</th>
<th>Sodium fluoride tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>In vivo</em> disintegration time (s)</td>
<td>20 ± 5</td>
<td>22 ± 2</td>
</tr>
</tbody>
</table>

*In vivo* disintegration time was measured below 1 minute.

Pharmacopoeial testing

ODT must disintegrate within 3 minutes, according to European Pharmacopoeia disintegration test conditions. *In vitro* disintegration tests according to major pharmacopoeias are performed in a large quantity of water, and therefore do not match exactly what happens in the mouth, where a limited quantity of saliva is available for disintegration.

No correlation exists between Pharmacopoeia disintegration test and *in vivo* disintegration test.

ODT tablets with PEARLITOL® Flash lead typically to disintegration times of less than 3 minutes using the Pharmacopoeial test, depending on the ODT formulation and the tablet size. The above described tablets were evaluated using Pharmacopoeial disintegration test. Results are given below.

<table>
<thead>
<tr>
<th></th>
<th>Hydrochlorothiazide tablets</th>
<th>Sodium fluoride tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>In vitro</em> disintegration time (s)</td>
<td>81 ± 13</td>
<td>70 ± 7</td>
</tr>
</tbody>
</table>

*In vitro* disintegration time was measured below 3 minutes.
In vitro test correlated with in vivo test

An *in vitro* test has been developed to mimic the *in vivo* disintegration, with excellent correlation.

A charge of 3N is applied on top of an ODT. Two millilitres of water are added (equivalent to the saliva volume). The change in charge is recorded. As the tablet disintegrates, charge decreases. The typical curve obtained is given for illustration.

Quick disintegration of PEARLITOL® Flash ODTs makes possible “On-the-go” use and quick onset of action.
Easy formulation
With PEARLITOL® Flash, formulation is simplified because fewer excipients are required:

- no superdisintegrant
- minimum level of lubricant
- minimum quantity of intense sweeteners or flavours

**Easy formulation**

**VITAMIN B12 ORODISPERSIBLE TABLETS WITH PEARLITOL® FLASH MANNITOL**

**FORMULA**

<table>
<thead>
<tr>
<th></th>
<th>% (by weight)</th>
<th>mg/tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEARLITOL® FLASH mannitol</td>
<td>96.054</td>
<td>508.08</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>0.004</td>
<td>0.02</td>
</tr>
<tr>
<td>Fruit berry flavor</td>
<td>0.002</td>
<td>0.01</td>
</tr>
<tr>
<td>Aspartame</td>
<td>0.002</td>
<td>0.01</td>
</tr>
<tr>
<td>Coloring agent FD&amp;C Red No 40</td>
<td>0.040</td>
<td>0.21</td>
</tr>
<tr>
<td>Coloring agent Patent Blue V</td>
<td>0.002</td>
<td>0.01</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>0.000</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**METHOD**

- Solubilize vitamin B12 in 10ml ethanol.
- Spray the solution on PEARLITOL® Flash mannitol in an Aeromatic at 20°C.
- Dry for another 10 min after the spraying stopped.
- In a mixer, mix the obtained dry powder, flavor, colors and aspartame for 5 minutes.
- Add magnesium stearate and mix for 5 minutes.
- Compress the powder in a single punch press fitted with 13mm flat bevilled edge punches.

**COMMENTS**

- Weight: 520 mg
- Thickness: 3.0 mm
- Density: 1.31
- Schleicher hardness: 80 N
- In vivo disintegration time: 20 s

Roquette: PEARLITOL® Flash: Melt-in-the-mouth magic with mannitol!
Roquette | PEARLITOL® Flash: Melt-in-the-mouth magic with mannitol
Definition and regulation

PEARLITOL® Flash is a compound of mannitol and extra white maize starch. Both ingredients comply with pharmaceutical and food regulations and can be used for pharmaceutical and nutraceutical orodispersible tablets.

Powder characteristics

PEARLITOL® Flash is designed for Direct Compression orodispersible tablets. It has excellent flow properties.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulk density (g/ml)</td>
<td>0.52</td>
</tr>
<tr>
<td>Tapped density (g/ml)</td>
<td>0.62</td>
</tr>
<tr>
<td>Haussner ratio</td>
<td>1.19</td>
</tr>
<tr>
<td>Angle of repose (°)</td>
<td>43</td>
</tr>
<tr>
<td>Ability to settle (ml)</td>
<td>16</td>
</tr>
<tr>
<td>Flowability (funnel, s)</td>
<td>5.5</td>
</tr>
<tr>
<td>Loss on drying (%)</td>
<td>1.1</td>
</tr>
</tbody>
</table>

*Indicative values; Hosokawa and Pharmacopoeia funnel test.*
**Particle size**

- $D_{10} (\mu m) = 80$
- Mean diameter ($\mu m$) = 200
- $D_{90} (\mu m) = 300$

*Indicative values; Beckman Coulter Laser Particle size analyser.*

**Low hygroscopicity**

PEARLITOL® Flash is stable to humidity as illustrated in the figure below.
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XYLISORB® DC: key benefits

XYLISORB® DC gives smooth chewable tablets with
- an attractive mouthfeel resulting from the singular combination of its refreshing taste and smooth texture
- flexibility in formulation, with this robust DC ingredient
- reliability of a pharma supplier

XYLISORB® DC is part of the Roquette Direct Compression polyols range, which includes sorbitol, maltitol, mannitol and other xylitol powders.

Create pleasant smooth chewable tablets with new XYLISORB® DC

XYLISORB® DC is a new granulated xylitol specifically designed for Direct Compression of smooth chewable tablets.

www.roquettenutra.com

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**A directly compressible granulated xylitol**

**Powder characteristics**

- Aerated bulk density (g/ml) 0.71
- Tapped bulk density (g/ml) 0.79
- Compressibility (%) 10
- Flowability funnel (time, s) 6
- Angle of repose (°) 43

**Slightly hygroscopic powder**

- Dynamic Vapor Sorption at 20°C

- XYLISORB® DC Xylitol freshness is a combination of its high solubility at mouth temperature and negative heat of dissolution. This intense refreshing effect combines well with cool flavors such as mint. Xylitol sweetness is equivalent to sucrose’s one, which gives the tablet an astonishing sweet cool taste.

**Burst of freshness**

XYLISORB® DC Xylitol gives a very smooth texture to the chewable tablets, that almost melt in the mouth. Whether used alone or in combination with other polyols of Roquette portfolio, XYLISORB® DC offers the formulator a full palette of textures.

**Formulation example**

**INDICATIVE VALUES**

**Particle size adapted to smooth chewable tablets**

- Beckman Coulter Laser
- Particle size analyser

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>D₅₀ (µm)</td>
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<td>Mean (µm)</td>
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<tr>
<td>D₉₀ (µm)</td>
<td>4.60</td>
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</tbody>
</table>

**Excellent compactibility**

- Fette P1000 rotary press, biconvex tablets, 10 mm diameter, 5 mm thickness, 1% Mg stearate

**For appealing smooth chewable tablets**

**For smooth texture tablets**

**Nutrition benefits**

XYLISORB® DC Xylitol provides also benefits thanks to

- Well established dental benefits
- Low calorie ingredient
- Low glycaemic index

These nutrition benefits are valuable in nutraceutical applications.

**Formulation benefits**

XYLISORB® DC Xylitol provides benefits for the formulator thanks to

- easy-to-use ingredient
- natural origin ingredient
- stability and compatibility
- reliability
- formulation flexibility enabling creativity